European Chemicals Agency

Decision number: CCH-D-0000000546-74-07/F
Decision date: 31 August 2010

**DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006**

**For *Silicic acid, titanium salt*, *CAS 42613-21-8 (EC Nr. 255-911-8)*; Registration Numbe**[redacted]

**Addressee**[redacted]

I. Procedure

Pursuant to Article 41(1) of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation) the European Chemicals Agency (ECHA) has performed a compliance check of the registration dossier for ***Silicic acid, titanium salt, CAS 42613-21-8 (EC Nr. 255-911-8)*** submitted by [redacted] (the "Registrant").

The Registrant submitted to ECHA a registration dossier for the substance for a tonnage band of 100-1000 tonnes per year. The registration number of this dossier is [redacted] and the registration date is 5 December 2008. The latest submission number [redacted]

The compliance check was initiated on 25 March 2009.

A communication letter was sent to the registrant on 27 July 2009 requesting clarifications regarding the registered substance to allow ECHA an accurate evaluation of the dossier. The registrant was given 30 days to address the questions mentioned in the letter, but no response or update of the dossier was provided to date.

On 12 March 2010, ECHA notified the registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision. The registrant has not responded or updated the dossier to date.

On 11 June 2010 ECHA notified the competent authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals to amend the draft decision within 30 days. Subsequently, competent authorities of the Member States submitted comments, which did not include proposals for amendments on the draft decision. Following Article 51(3) of the REACH Regulation, ECHA

has therefore taken the decision concerning the present compliance check as notified to the Member State competent authorities and issued on 11 June 2010.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

Information required

ECHA has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of the REACH Regulation:

1) Pursuant to Articles 41(1)(a), 41(3) and 10(a)(ii) as well as Annex VI , Section 2 of the REACH Regulation the registrant shall submit for the registered substance

   a. Information enabling verification of the composition of the substance (Annex VI, 2.3) and in particular,
      - an elementary analysis by appropriate analytical methods
      - [redacted] in the substance
   b. Information enabling verification of the analytical methods used for the identification of the substance and for the identification of the impurities and additives (Annex VI, 2.3.7) and in particular:
      - a description of the analytical methods used for the identification of the substance and for the identification of the impurities and additives
      - information relating to the recording conditions for the Si-NMR and infra-red spectra
   c. Information clarifying the structural and molecular formula of the substance (Annex VI, 2.2.1.)

Pursuant to Article 41(4) of the REACH Regulation the registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by 01/03/2011

II. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the registrant for registration of the above mentioned substance in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Articles 10 and Annex VI thereof. Consequently, the registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

In detail:

1) Missing or incomplete information related to substance identity

Pursuant to Article 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation, the technical dossier of the registration shall include information on the identity of the substance. Annex VI, Section 2 lists information requirements that shall be sufficient to identify the registered substance.

a. Verification of the composition of the substance (Annex VI, 2.3.):

The registration did not contain sufficient information to enable to identify the substance. Information about the determination of the qualitative and quantitative composition was not provided.

(i) The spectral data provided (infrared spectrum and Si-NMR) are not sufficient to allow a verification of the quantitative composition of the substance. Therefore the composition, the concentration ranges of the main constituent and impurities cannot be confirmed.

The registrant should therefore provide an elementary analysis by appropriate analytical methods, e.g. Atom Absorption Spectroscopy (AAS), for each element present in the substance in order to verify the substance composition and identity. The registrant is also required to provide information on the results and methods used for the determination of all impurities. The registrant should update section 1.4 of the substance dataset with the required information.

(ii) Furthermore the registrant has indicated [redacted] as an additive with the function as a catalytic agent. However, catalytic agents are not regarded as additives necessary to preserve the stability of the substance. Therefore [redacted] should normally not be regarded as a constituent of the substance.

The registrant should therefore justify why a catalytic agent is necessary for preserving the stability of the substance. The registrant should also clarify whether [redacted] is part of silicic acid, titanium salt or whether [redacted] was added intentionally to the substance which would result in forming a mixture. In the latter case [redacted] would also need to be registered if the relevant registration tonnage thresholds have been met. The registrant shall update section 1.2 of the substance dataset with the required information.

b. Verification of the analytical methods used for the identification of the substance and for the identification of the impurities and additives (Annex VI, 2.3.7):

A description of the analytical methods used for the identification of the substance and for the identification of the impurities and additives is missing.

The registrant should provide a description of the analytical methods used for the identification of the substance and for the identification of the impurities and additives. Such description must be sufficient to allow the analytical methods used to be reproduced.

Moreover, the registrant has not indicated recording conditions for the Si-NMR and infra-red spectra. Therefore the spectral data cannot be interpreted and as a consequence the identity of the substance cannot be confirmed.

The registrant should therefore provide the following recording conditions for the Si-NMR spectrum, namely internal standard, solvent, concentration of the test solution and frequency and for the infra-red spectrum concentration of the test substance (if appropriate), method of preparation of the sample and reference solvent (if appropriate).

The registrant shall update section 1.4 of the substance dataset with the required information.

c. Clarification regarding the structural formula and molecular formula (Annex VI, 2.2.1.):

The molecular formula derived from the structural formula would [redacted] However, the molecular formula is given with [redacted] As no analytical data is provided on the chemical composition of the substance, the indicated molecular formula cannot be confirmed and additional information is required to clarify this.

Therefore the registrant should provide an elementary analysis as recommended in point a. "Verification of the composition of the substance (Annex VI, 2.3)".

The registrant shall update section 1.1 of the substance dataset with the required information.

III. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Done at Helsinki,

[redacted]

Geert Dancet
Executive Director